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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,965	05/18/2000	MARTHA A. WARPEHOSKI	0769-0420-OX	3222

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EXAMINER	
LIU, HONG	
ART UNIT	**PAPER NUMBER**
1624	9

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/530,965	Warpehoski et al.
Examiner	**Art Unit**
Hong Liu	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-19 is/are pending in the applica

4a) Of the above, claim(s) 4 and 6 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3, 5, and 7-19 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-19 are pending in this application.

Election/Restriction

Applicants' election of Group I subject matter with traverse in Paper No. 6 is noted but is not persuasive for the following reasons. Restriction is proper when there is a lack of unity of invention and such is not affected by the manner of claiming-i.e. in separate claims or within a single claim. As stated in the previous action the resultant compounds constitute structurally dissimilar compounds. Placing all such compounds into the same claim is repugnant to scientific classification as they are separately classified and require separate literature searches. Having a common utility among the groups is not enough where as herein there is not a substantial structure feature common to all groups. They are made and used independently of each other, are not art-recognized equivalents. Such traverse of the restriction requirement is not consistent with applicants' urging of patentability over the art cited below which is much closer to some of the claimed compounds than they in turn are to each other.

1. For the above reasons, the restriction is still deemed proper and is therefore made FINAL.

Claims 4 and 6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 7-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Freskos et al. (WO 98/39326). Freskos teaches the compounds, composition, and use of the instant invention (see Examples).

4. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

> such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freskos et al. (WO 98/39326). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, page 8 wherein R2 is hydrocarbyl, (N-morpholino)methyl, (N-pyrrolidino)methyl, or (N-thiomorpholino)methyl, R1 is cycloalkyl, heterocycle, aryl, etc. The compounds are taught to be useful as matrix metalloproteinase inhibitors. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

6. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-3, 5, 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bender et al. (EP 0780386). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, page 4 wherein Y is XONH wherein X is hydrogen, R1 can be lower alkyl, R2 can be NR6R7, R3 and R4 can be both hydrogen, R5 is cycloalkyl, aryl, or heteroaryl, etc. The compounds are taught to be useful as matrix metalloproteinase inhibitors. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for blocking stromelysin and gelatinase and treating gastric cancer, does not reasonably provide enablement for blocking collagenase and treating diseases related to connective tissue, gastric ulceration, inflammation, or asthma etc. Applicants provide no compelling evidence that instantly disclosed tests (on pages 26 and 27) are reasonably predictive for one use much less for the disorders listed in the claims. Applicants have not demonstrated a nexus between the activity of the compounds and the myriad of divergent utilities in claims 7-19 Furthermore, search of the recently published literature on matrix metalloproteinase inhibitors reveals no teaching of treatment of the diseases recited in claims 33-44. Steward (Cancer Chemother. Pharmacol., 1999), for instance, point outs that Marimastat, the first matrix metalloproteinase inhibitor that has entered clinical trial, has only some effects on gastric cancer. The phase II study of the drug, particularly in gastric cancer "suggest that matrimastat may have biological activity which reduces tumor growth, but firm evidence of an effect on clinical outcome is still not available." page 59. In addition, the claims also do not recite the expected result. Contrary to what applicants urge is enabled, there is no art-recognized evidence of clinical

efficacy for the scope being claimed. See Ex parte Powers 220 USPQ 925 for establishing in vivo efficacy. Competent evidence of art-recognized efficacy for claimed uses needs to be provided.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

9. 1). Claim 9 is of indeterminate scope for more than one reason. First, no one particular disorder is recited. Second, the claim language may read on diseases not yet fully understood to be affected by matrix metalloproteinase. In addition, how does one determine who is "in need of such treatment" and who is not. Specification appears to give no guidance to the answer.

2). Claim 8 is indefinite as it contains the phrase "comprise."

10. 3). Claim 16 is a substantial duplicate of Claim 1, as the only difference is intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.

11. 4). Claims 17-19 provide for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
February 7, 2002

Mukund J. Shah

Mukund Shah
Supervisory Patent Examiner
Art Unit 1624